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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,368	09/28/2004	Joachim Bunger	MERCK-2926	3834

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EXAMINER	
HUGHES, ALICIA R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
09/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,368	BUNGER ET AL.	
	Examiner	Art Unit	
	ALICIA R. HUGHES	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,12,14-16 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,12,14-16 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 3, 12, 14-16, and 20-24 are pending and the subject of this Office Action. Claims 1-2, 4-11, 13 and 17-19 have been cancelled. Applicants, in their filing of 15 June 2009, added new claims 21-24.

Applicants' arguments, filed on 18 June 2010, have been fully considered, but are not deemed to be persuasive regarding the previous rejection. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Claim Objections

As noted prior, claims 14 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. As the claims have not been rewritten in independent form, they remain objected to for the reason already made of record.

Claim Rejection – 35 U.S.C. §103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

> such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 12, 15-16, and 20-21 and 23-24 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Pre-Grant Publication No. 2002/0106337 A1 [hereinafter referred to as "Deckers et al"].

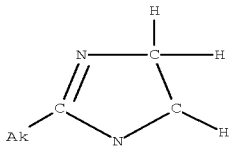
The teachings of Dekkers et al from this Office's previous actions are incorporated herein by reference in total.

Applicants argue that Miracare BT is a surfactant commonly used in cleansing and washing preparations and that there is no reasons why a skilled person would have considered significantly altering the chemical structure of this ingredient to subsequently use it in a method for the protection of human skin against wrinkling. While the Examiner appreciates this argument, the same is but an allegation that lacks factual support and further, does not speak to the merits of the rejection as filed.

As noted prior, Deckers et al teach emulsion formulations for topical application that is very mild to the skin and therefore easily formulated into a wide variety of personal care and dermatological products. The active agents in the invention, of which Miracare BT is one (See

Page 20, Para 236 and 237; see also Page 22, Paras 238, 240 and 242), are generally present in an amount that "varies from about 0.0001% (w/v) to about 50% (w/v). Deckers et al also teach that oil body emulsions of their invention may be advantageously formulated with anti-wrinkle and anti-aging actives (Page 11, Para. 125) and that further, personal care products, such as hair care products and suncare products may be used "for treatment or reversal of skin changes associated with aging such as wrinkles" (Page 13, Para. 166). These products may include anti-wrinkle cream (Page 14, Paras. 167 and 175).

In preparing a STN Search in association with examining this application, the examiner prepared the following core structure, consistent with substituents specified by Applicants therein:



which revealed Miracare BT, which upon review is an active ingredient in Deckers et al, as referenced above.

With regard to claims 20 and 24, Applicants require the administration of an isolated stereoisomeric form of the compound. It is important to note however, that as a matter of law, compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds

possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). *See also In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *prima facie* obvious). The necessary motivation to make the claimed compound, and thus the *prima facie* case of obviousness, arises from the reasonable expectation that compounds similar in structure will have similar properties. *In re Gyurik*, 596 F.2d 1012, 1018 (CCPA 1979). *See also Daiichi Sankyo v. Apotex*, 84 USPQ 1285 (Fed. Cir. 2007): reference taught that ciprofloxacin lacked ototoxicity when used to treat middle ear infections; another reference taught that ofloxacin and ciprofloxacin are both gyrase inhibitors and belong to the same family of compounds; court held that it would have been obvious to one of ordinary skill in the art to substitute ofloxacin for ciprofloxacin in the treatment of othopathy with a predictable expectation of successful treatment due to the compounds' structural and functional similarities (note: this a post-KSR case).

Optimization of the acid addition salt formulation for an active pharmaceutical ingredient is obvious where the acid addition salt formulation has no effect on the therapeutic effectiveness of the active ingredient and the prior art suggests the particular anion used to form the salt. Pfizer v. Apotex, 82 USPQ2d 1321, 1336 (Fed. Cir. 2007). Moreover, one skilled in the art would expect various anions to provide salts having a range of properties, some of which would be superior, and some of which would be inferior, to any given salt. Id. 1338. (note: this is a post KSR case)

As legal authority the Examiner cites In re Adamson, 125 USPQ 233 (CCPA 1960). The case sets forth the requirements of patentability with regard to stereoisomers as follows:

> 1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See p. 235, ¶ 1.

2) One skilled in the art expects that individual stereoisomers will differ significantly physiological/pharmacologic activity and toxicity, because living systems are chiral and thus preferentially process certain stereochemical configurations over others. See p. 234, third full paragraph, and p. 235, fifth full paragraph.

As such, the disclosure in Deckers et al brings the instant claims within the purview of the previously disclosed art.

In view of the foregoing, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to administer the compounds in claims 3, 12, 15-16, and 20-21 and 24 to protect human skin against wrinkles.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 A.M. until 5:00 P.M. on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application is proceeding is assigned 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614